PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
IYDS:205262085		
International Application No.	International Filing Date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/AU2003/001573	26 November 2003	27 November 2002

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] C12N 5/02, C12N 15/01

Applicant

HUMAN GENETIC SIGNATURES PTY LTD et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
5 May 2004	28 July 2004
Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**Gillian Allen** Telephone No. (02) 6283 2266

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/001573

Basis of the report

With regard to the **elements** of the international application:*

- [ ] the international application as originally filed.
- [X] the description, pages **1-33** as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [X] the claims, pages as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages , filed with the demand,
  pages **34 and 35** received on **21 July 2004** with the letter of **21 July 2004**
- [X] the drawings, pages **1/5-5/5** as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:
   - [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
   - [ ] the language of publication of the international application (under Rule 48.3(b)).
   - [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
   - [ ] contained in the international application in written form.
   - [ ] filed together with the international application in computer readable form.
   - [ ] furnished subsequently to this Authority in written form.
   - [ ] furnished subsequently to this Authority in computer readable form.
   - [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [X] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [X] the claims, Nos. **21**
   - [ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**1-20**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-20**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-20**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 Pietrobono R *et al, Nucleic Acids Research*, July 2002, 30(14):3278-3285

Novelty (N) and Inventive Step (IS).

D1 discloses the treatment of cell lines with 5azadC to activate the FMR1 gene through altering the methylation, the absence of the FMR1 protein leading to fragile X syndrome. The methylation patterns of the cell are examined after treatment with 5azadC.

However, the citation does not teach the use of cell lysates from one cell to alter cell characteristics of another cell, and determination of such alteration by comparing methylation patterns. Nor would it be in any way obvious to derive such methods from the disclosures of the description methylation patterns.

Therefore all claims are accepted as novel and inventive.

Claims:

1. A method for altering a characteristic or state of a cell comprising:

treating a first cell type with an agent capable of altering a characteristic or state in a cell, wherein the agent is an extract, lysate, cellular component or mixture thereof derived or obtained from a second cell type having a desired characteristic or state; and

determining the degree of alteration in the treated cell by measuring a methylation signature within the genome of the treated cell, wherein a given methylation signature is indicative of an altered characteristic or state of the treated cell.

2. The method according to claim 1 wherein the first cell type is selected from the group consisting of a cell derived from an individual suffering from age-related disabilities, a disease such as cancer, an autoimmune disease, cardiovascular problems such as myocardial infarction or ischemia, stem cell, T cell or monocyte of the immune and hematopoietic system, normal cell, and mixtures thereof.

3. The method according to claim 2 wherein the first cell type is a stem cell.

4. The method according to any one of claims 1 to 3 wherein the second cell type is any cell type or combination of cell types.

5. The method according to claim 4 wherein the second cell type is selected from the group consisting of a cell derived from a healthy individual, stem cell, T cell or monocyte of the immune and hematopoietic system, normal cell, and mixtures thereof.

6. The method according claim 4 wherein the first and second cell types are selected from the group consisting of cells of the human haematopoietic system, stem cells, and epithelial cells.

7. The method according claim 6 wherein the second cell type is derived from a normal or healthy individual of a cell type similar to the first cell type.

8. The method according claim 7 wherein the second cell type is a stem cell.

9. The method according to any one of claims 1 to 8 wherein the first cell type cell and the second cell type cell are of the same cell type from the same species.

10. The method according to any one of claims 1 to 8 wherein the first cell type and the second cell type are not of the same cell type.

11. The method according to any one of claims 1 to 8 wherein the first cell type and the second cell type are not of the same species.

12. The method according claim 11 wherein the second cell type is an amphibian cell and the first cell type is human or other mammalian cell.

13. The method according to any one of claims 1 to 12 wherein the first cell type is pre-treated so as to make the cell permeable to macromolecules.

14. The method according to claim 13 wherein the cell is pre-treated by electroporation, low temperature thermal shock, or various enzymes such as streptolysin O.

15. The method according to claim 14 wherein the pre-treatment renders the cell temporally permeable.

16. The method according to any one of claims 1 to 15 further including:

culturing or growing the treated cell to obtain multiple copies of the treated cell.

17. The method according to claim 16 wherein the treated cell is cultured in any suitable media or host under conditions that are suitable for cell growth and division.

18. The method according to claim 17 wherein the host is a domestic animal selected from the group consisting of bovine, ovine, equine, poultry, and porcine.

19. The method according to any one of claims 1 to 18 wherein the methylation signature is a group of cytosines within a region of the genome that has a characteristic methylation signature which corresponds to a specific cell type.

20. The method according to any one of claims 1 to 19 wherein the methylation signature is determined by the bisulphite modification and subsequent DNA sequence analysis.